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# THE LIABILITY OF NOTIFIED BODIES UNDER THE EU'S NEW APPROACH: THE IMPLICATIONS OF THE PIP BREAST IMPLANTS CASE (C-219/15)

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## Abstract

In this article, we analyse the consequences of the CJEU's judgment in *Schmitt*, a preliminary reference concerning the potential liability of the notified body TÜV Rheinland vis-à-vis women who had received breast implants produced by the French manufacturer Poly Implant Prothèse SA ("PIP"). Our discussion focusses on (i) the impact of the judgment on the damages actions women have brought against TÜV Rheinland before national courts; (ii) the future regulation of medical devices in the EU; and (iii) the regulation of private standardisation and certification in EU law. We argue that *Schmitt* can be seen as part of a broader trend in the case law of the CJEU, in which private regulatory activities are gradually submitted to fundamental principles of EU law. While this 'constitutionalisation' of private regulation strengthens the public accountability of these alternative forms of regulation, it also poses fundamental challenges to their current design and internal governance.

## Introduction

In February 2017, the Court of Justice of the European Union (“CJEU” or “Court”) delivered its judgment in *Schmitt*, a preliminary reference on the potential liability of the notified body TÜV Rheinland (“TÜV”) vis-à-vis women who had received breast implants produced by the French manufacturer Poly Implant Prothèse SA (“PIP”).<sup>1</sup> The claimant, Ms Schmitt, was one of the many thousands of women who have fallen victim to the fraudulent activities of PIP. *Schmitt* concerns a key question in the legal aftermath of the so-called PIP breast implants scandal: is TÜV, as a private certification body which conducted inspections required by EU law at PIP’s factory, liable for the material and immaterial harm suffered by women who received PIP breast implants?

In this article, we will focus on the question of what – actual and potential – implications the CJEU’s judgment has in relation to four issues. First of all, we discuss the relationship between the New Approach, the regulatory framework in which breast implants are placed on the EU market, and civil liability of certification bodies. Second, we analyse the impact of the judgment on damages actions brought by Ms Schmitt and other women against TÜV before national courts. We then consider how the judgment relates to the future regulation of medical devices in the EU under the new rules that will apply from 2020. Fourth and finally, we identify a broader trend in the case law of the CJEU, of which *Schmitt* is a recent example: the “constitutionalisation” of private regulation. The judgments in *Fra.bo* and *James Elliott* already broke new ground in gradually submitting private standardisation and certification activities to fundamental principles of EU law, and we will discuss what *Schmitt* adds to this trend.

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<sup>1</sup> *Elisabeth Schmitt v TÜV Rheinland LGA Products GmbH* (C-219/15), ECLI:EU:C:2017:128.

However, before the implications of *Schmitt* are analysed, we have to provide some context to the analysis. Therefore, we first discuss the background to the PIP breast implants scandal, the applicable regulatory framework and the CJEU's judgment.

### **The PIP breast implants scandal**

PIP was a well-known manufacturer of silicone breast implants.<sup>2</sup> It was based in France and founded in 1991, but soon started to operate on a worldwide basis. Around 2000, the management of PIP decided to save costs on the type of silicone gel used in breast implants. Instead of the required medical silicone gel, PIP started to use a much cheaper type of industrial silicone gel in breach of the relevant French and European safety standards. PIP did so on an entirely random basis – some breast implants were filled with the required medical silicone gel, while others were filled with industrial silicone gel. It managed to cover the use of industrial silicone gel for a substantial period of time. PIP successfully kept its purchases of significant amounts of industrial silicone gel outside its business records and falsified invoices to make it look like the expected amount of medical silicone gel had been bought. In 2009, the French public supervisory agency received information about potential problems with the breast implants manufactured by PIP. In 2010, criminal investigations were started, which eventually led to the discovery of the fraud. PIP's breast implants were immediately taken off the market. PIP was declared bankrupt in 2010. Moreover, the management of PIP was sentenced to lengthy sentences of imprisonment.

By the time of the discovery of the fraud in 2010, hundreds of thousands of women all over the world had already received PIP breast implants. In the absence of adequate national systems to register the use of breast implants, many women who received breast implants could not be certain whether their implants had actually been manufactured by PIP. Even if they did know,

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<sup>2</sup> For more background, see B. van Leeuwen, "PIP Breast Implants, the EU's New Approach for Goods and Market Surveillance by Notified Bodies" (2014) 5 European Journal of Risk Regulation 338 and P. Rott and C. Glinski, 'Ramsch-Brustimplantate: Ein Lehrstück europäischer Produktsicherheit', in: C. Joerges, T. Pinkel and U. Uetzmann (eds.), *Josef Falke zum 65. Geburtstag* (Bremen: Zentrum für Europäische Rechtspolitik 2014), pp. 137-152.

they could not know whether their breast implants contained industrial silicone gel due to the random nature of PIP's fraud. The only way to find out was for the breast implants to be removed. Because preliminary studies indicated that PIP breast implants showed significant higher rates of rupture and "gel bleed",<sup>3</sup> and several public health safety agencies thus advised women to have their implants removed or replaced, many victims indeed decided to undergo surgery. As a result, they claimed to have suffered both material and immaterial damage.

Because PIP went bankrupt in 2010, it was not realistic for victims to bring a direct action against the manufacturer. As a result, victims had to search for alternative strategies to obtain compensation. They have started legal proceedings in different European jurisdictions against a whole range of parties involved in the production, distribution and medical use of PIP breast implants.<sup>4</sup> While some victims decided to bring an action against PIP's insurer, Allianz, others decided to claim compensation from the doctors who had placed the breast implants, or the clinics and hospitals where the implants had been placed. Because of many legal and practical issues that came up in bringing these cases to court (e.g. private international law issues, evidential issues and problems with the solvency of defendants), another group of victims decided to hold the national public health agency liable for a failure to adequately supervise the trade in medical devices and to protect end users against unsafe breast implants. Finally, in Germany and France, a number of individual cases and group litigation claims were brought against TÜV, the certification body that carried out conformity assessments which PIP was required to undergo based on EU law before it could place its breast implants on the EU market. One such case in Germany has now resulted in a judgment by the CJEU in *Schmitt*. This

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<sup>3</sup> European Commission, Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), "Opinion on the safety of Poly Implant Prothèse (PIP) Silicone Breast Implants": [http://ec.europa.eu/health/scientific\\_committees/emerging/docs/scenihr\\_o\\_043.pdf](http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_043.pdf), p. 52.

<sup>4</sup> See in detail, Van Leeuwen, "PIP Breast Implants, the EU's New Approach for Goods and Market Surveillance by Notified Bodies" (2014) 5 European Journal of Risk Regulation 338, 341-346, P. Rott and C. Glinski, "Die Haftung der Zertifizierungsstelle im Produktsicherheitsrecht" (2015) Zeitschrift für Europäisches Privatrecht 192, 196-199, P.W.J. Verbruggen and B.J. van Leeuwen, "Europese regelgeving inzake medische hulpmiddelen: Het PIP-schandaal, de 'Nieuwe Aanpak' en consumentenbescherming" (2015) Tijdschrift voor Consumentenrecht en Handelspraktijken 111 and J. De Bruyne and C. Vanleenhove, "Liability in the Medical Sector: The 'Breast-Taking' Consequences of the Poly Implant Prothèse Case" (2016) 24 European Review of Private Law 823.

judgment will have a significant impact on the outcome of other cases and will, therefore, be the main focus of this article. However, before we can fully address the CJEU's judgment, the EU's regulatory framework for breast implants should be explained.

### **The regulatory framework of the New Approach**

TÜV is a private certification body incorporated in Germany, with subsidiaries around the world. It provides global certification services to assess and control the conformity of products, services, staff, manufacturing processes and quality management systems. TÜV had concluded a contract with PIP to carry out conformity assessment procedures regarding PIP's breast implants. The Medical Devices Directive required this conformity assessment procedure to take place before PIP could place its products on the market.<sup>5</sup> As such, this Directive regulated the production of and trade in breast implants on the European market.

The Medical Devices Directive is part of the so-called New Approach, a legislative programme developed in the 1980s to improve the free movement of goods in the EU.<sup>6</sup> With the New Approach, the EU adopts directives and regulations in which the essential requirements with which products have to comply are laid down. The precise technical specifications are then laid down in a European harmonised standard that is developed by one of the European standardisation bodies – CEN, CENELEC or ETSI. After the European Commission has published a reference to this standard in the Official Journal of the EU ("OJEU"), a presumption arises that products which comply with the harmonised standard also comply with the essential requirements of the relevant directive. As such, establishing compliance with a harmonised standard has become the main way for manufacturers to show that their products comply with

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<sup>5</sup> Council Directive 93/42/EEC of 14 June 1993 concerning medical devices [1993] OJ L 169/1. The European Parliament and Council recently adopted two Regulations which will replace the Directive in the course of 2020. See [http://europa.eu/rapid/press-release\\_MEMO-17-848\\_en.htm/](http://europa.eu/rapid/press-release_MEMO-17-848_en.htm/).

<sup>6</sup> See, in general, (and with further references) H. Schepel, *The Constitution of Private Governance* (Oxford: Hart Publishing, 2005), pp. 227-246, C. Hodges, *European Regulation of Consumer Product Safety* (Oxford: Oxford University Press 2005), pp. 53-73 and, most recently, B. van Leeuwen, *European Standardisation of Services and its Impact on Private Law* (Oxford: Hart Publishing, 2017), pp. 40-47.

the relevant European legislation. Although it is possible for manufacturers to show that they comply with the European legislation through other means, in practice most manufacturers choose to show that their products comply with the European standard.<sup>7</sup>

In order to show that their products satisfy the requirements of the European legislation, manufacturers have to place a CE marking on their products. For certain categories of products which are not considered risky, manufacturers can place the CE marking on their products without any pre-market control by external parties. For other products in a higher risk category, the manufacturer cannot individually place the CE marking on their products. In these cases, a “notified body” will carry out a conformity assessment procedure to verify whether the products comply with the European harmonised standard. The term “notified bodies” is used because these certification bodies have been notified to the European Commission by the Member State in which they are based. Certification bodies are then considered competent to carry out conformity assessment procedures for a particular directive. As a result, there is a European list with notified bodies for each directive adopted under the New Approach. Most of the notified bodies – including TÜV Rheinland – are private, but some of the notified bodies are public bodies.<sup>8</sup>

For the Medical Devices Directive, the obligations of notified bodies are set out in Annex II. Essentially, they can be divided in three categories: first, notified bodies have to inspect the quality system of the manufacturer;<sup>9</sup> second, they have to inspect the design dossier;<sup>10</sup> third, they have to undertake surveillance to ensure that the manufacturer continues to comply with the quality system.<sup>11</sup> If the conformity assessment procedure is successful, the notified body has to

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<sup>7</sup> Van Leeuwen, *European Standardisation of Services and its Impact on Private Law* (Oxford: Hart Publishing, 2017), 42. See also H. Schepel, “The new approach to the New Approach: the juridification of harmonised standards in EU law” (2013) 20 *Maastricht Journal of European and Comparative Law* 521, 528.

<sup>8</sup> J.-P. Galland, “The Difficulties of Regulating Markets and Risks in Europe Through Notified Bodies” (2013) 4 *European Journal of Risk Regulation* 365, 368.

<sup>9</sup> Article 3 of Annex II of the Medical Devices Directive.

<sup>10</sup> Article 4 of Annex II of the Medical Devices Directive.

<sup>11</sup> Article 5 of Annex II of the Medical Devices Directive.

provide to the applicant manufacturer a declaration of conformity, which enables the manufacturer to place the CE marking on its products and place their products on the European market.

The various cases brought against TÜV essentially focussed on the precise obligations of TÜV based on its contractual arrangement with PIP. More specifically, they concerned the question of whether TÜV – either based on the contract with PIP or directly on the national legislation which had implemented the Medical Devices Directive – owed a duty of care towards the end users of PIP breast implants – the women who suffered harm after they had received these implants.

### **The Judgment in *Schmitt***

#### *The factual background and the German proceedings*

In 2008, Elisabeth Schmitt received PIP breast implants in a private clinic in Germany. After the PIP scandal emerged in 2010, and more was revealed about the health risks associated with the use of industrial silicone gel, Ms Schmitt decided to have her implants removed. She could not prove that her breast implants contained industrial silicone gel. Nevertheless, she brought an action against TÜV Rheinland.

Ms Schmitt claimed that if TÜV had performed its inspections and audits of PIP more strictly, and if it had used all powers provided to it under the Medical Devices Directive, it would have discovered the irregularities in PIP's manufacturing process. Between 1998 and 2008, TÜV had carried out eight conformity assessment procedures at the PIP factory. On each occasion, TÜV had provided a declaration of conformity to PIP. Therefore, PIP could continue to place its implants on the market. All eight visits had been announced to PIP – none of them had been unannounced inspections. Moreover, TÜV had never physically inspected the implants. It had never audited the business records of PIP either. Ms Schmitt argued that if such inspections had



taken place, the fraud committed by PIP would have been revealed much earlier and the harm to women who had received PIP breast implants would have been avoided. She claimed compensation of €40,000 for the pain and suffering and the costs for the removal and replacement of her breast implants. She also argued that TÜV should be held liable for any future damage which would not be covered by her health insurance.

In 2013, the German district court dismissed Ms Schmitt's claim for three reasons.<sup>12</sup> First of all, it held that she could not prove that she had suffered any harm. No evidence had been provided to suggest that she had suffered damage to her health. The sole risk that the breast implants could rupture was not sufficient to constitute harm. Secondly, Ms Schmitt had not provided any evidence to show that her breast implants contained industrial silicone gel. It would not have been difficult for her to have some testing done after the implants had been removed. Thirdly, the court held that TÜV had not breached any of its obligations under the Medical Devices Directive. It was under no obligation to carry out unannounced inspections, or to physically inspect the breast implants.

On appeal, the court took a more principled approach and held that, under German private law, TÜV did not owe a contractual duty of care or a duty of care in tort towards the women who had received PIP breast implants.<sup>13</sup> The aim of the conformity assessment procedure was to enable the manufacturer to place their products on the market. As a result, TÜV was not acting in the interests of women who received breast implants. The Medical Devices Directive did not impose obligations on TÜV vis-à-vis these end users. Even if TÜV did owe such a duty of care, the fraud committed by PIP had been so advanced that TÜV had not breached its duty. With its powers

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<sup>12</sup> Judgment of the Landgericht Frankenthal (Pfalz) of 14 March 2013 – 6 O 304/12, as discussed in detail by the authors cited in n 4 *supra*.

<sup>13</sup> Judgment of the Oberlandesgericht Zweibrücken of 30 January 2014 – 4 U 66/13. These contractual and extra-contractual grounds for liability concern the doctrine of *der Vertrag mit Schutzwirkung zugunsten Dritter* (a contract with protective scope for third parties) and § 823 II *Bürgerliches Gesetzbuch* (dealing with liability in tort for a breach of statutory rules) respectively. See, for more discussion, C. van Dam, *European Tort Law* (Oxford: OUP, 2013), 212.

under the Medical Devices Directive, it could not have been expected that TÜV had discovered the fraud.<sup>14</sup>

Ms Schmitt appealed to the highest civil court in Germany, the *Bundesgerichtshof*. Under German law, Ms Schmitt's chances of success depended to a significant extent on the purpose of the provisions of the Medical Devices Directive and the statutory rules implementing that directive in the national legal order (*Medizinproduktegesetz*)~~implementing measures on the conformity assessment procedure~~. German tort law requires~~d~~ that Ms Schmitt fell within the protective scope of these statutory provisions (*Schutzgesetz*) as a condition for the award of damages.<sup>15</sup> Therefore, the *Bundesgerichtshof* first of all asked the CJEU about the purpose and intention of the relevant provisions of the Directive. Was it the purpose and intention of the Directive that notified bodies responsible for the conformity assessment and surveillance act in order to protect all potential patients and may therefore, in the event of a culpable infringement of an obligation, have direct and unrestricted liability towards the patients concerned? The second and third question focussed on the precise obligations of TÜV under the Directive: are notified bodies under a general obligation to examine medical devices, or at least to examine them where there is due cause? Similarly, are notified bodies under a general obligation to examine the manufacturer's business records and/or to carry out unannounced inspections, or at least to do so where there is due cause?

### *The Judgment of the CJEU*

In February 2017, the CJEU delivered its judgment. It reversed the order of the questions of the *Bundesgerichtshof* and started by answering the second and third question together. The CJEU held that the Medical Devices Directive provides in detail how notified bodies have to act in

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<sup>14</sup> Rott and Glinski are very critical about the reasoning of the *Oberlandesgericht Zweibrücken* and claim that the court misread the aim of the Medical Devices Directive and its implementing legislation. See Rott and Glinski, "Die Haftung der Zertifizierungsstelle im Produktsicherheitsrecht" (2015) *Zeitschrift für Europäisches Privatrecht* 192, 204-208.

<sup>15</sup> § 823 II *Bürgerliches Gesetzbuch*.

assessing the design dossier and the quality management system of manufacturers. The Directive does not impose a general obligation on notified bodies to carry out unannounced inspections, to examine devices or to inspect the business records of manufacturers. It only makes it possible for notified bodies to carry out unannounced inspections or to take additional testing to check the quality management system. Furthermore, the Directive makes it possible to carry out inspections of the manufacturer and to request all information necessary to be able to make and maintain the declaration of conformity.<sup>16</sup>

In the exercise of their regulatory activities under the Medical Devices Directive, notified bodies must be allowed a certain degree of discretion. However, this degree of discretion is not unlimited and has to be “appropriate”.<sup>17</sup> Otherwise, notified bodies would be free “not to take any steps in the face of evidence indicating that a medical device might not comply with the requirements” laid down in the Directive.<sup>18</sup> If they did not act in the face of such evidence, they would be in breach of their obligations to take steps to withdraw, suspend or restrict the declaration of conformity whenever the requirements of the Directive are no longer met by the manufacturer.<sup>19</sup> Therefore, notified bodies are under a “general obligation to act with all due diligence” in the context of performing their tasks in the conformity assessment procedure.<sup>20</sup> As a result, they have to be alert and have to take appropriate action if they receive evidence which indicates that medical devices may not be complying with the requirements of the Directive.<sup>21</sup>

The first question of the Bundesgerichtshof was split in two parts by the CJEU. First, it assessed what the aim of the Medical Devices Directive was. Second, it analysed whether a breach of the obligations under the Directive could give rise to liability vis-à-vis women like Schmitt who had received breast implants. The CJEU held that the aim of the Directive is also to protect the end

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<sup>16</sup> *Schmitt* (C-219/15) at [40] – [43].

<sup>17</sup> *Schmitt* (C-219/15) at [45].

<sup>18</sup> *Schmitt* (C-219/15) at [45].

<sup>19</sup> Article 16(6) of the Medical Devices Directive.

<sup>20</sup> *Schmitt* (C-219/15) at [46].

<sup>21</sup> *Schmitt* (C-219/15) at [47].

users of medical devices.<sup>22</sup> While the primary duty to ensure that medical devices are safe and comply with the Directive is imposed on the manufacturer, the Directive also imposes obligations on the Member States and notified bodies. The surveillance obligations imposed on these actors ensure protection for the health and safety of persons who receive medical devices. This is consistent with the wording and overall scheme of the Directive. Therefore, the purpose of the involvement of notified bodies is to protect the end users of medical devices.<sup>23</sup>

The final issue was whether the aim of the involvement of notified bodies also meant that the Medical Devices Directive provided a right to patients to obtain damages from notified bodies. The CJEU held that the Directive does not create such a right. The Directive does not contain any provisions which grant a right to end users to hold notified bodies liable.<sup>24</sup> Reference was made to *Paul*,<sup>25</sup> in which the CJEU had held that EU legislation on the supervision of financial markets – the aim of which was to protect depositors – did not grant depositors a right to claim damages from supervisory agencies. Moreover, the CJEU held that the Directive did not aim to regulate the conditions under which notified bodies could be held liable. The fact that it imposed an obligation on notified bodies to take out civil liability insurance could not be used to claim that end users were granted a right of compensation, since no further details were provided on why the insurance had to be taken out.<sup>26</sup> The Product Liability Directive, which provides for strict liability of manufacturers for personal injury and damage to property caused by defective products, did not exclude the possibility of other (national) systems of fault-based liability. Therefore, as the Court considered, the conditions under which notified bodies are liable to end users for a wrongful act – a culpable failure to fulfil their obligations under the Medical Devices

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<sup>22</sup> *Schmitt* (C-219/15) at [50].

<sup>23</sup> *Schmitt* (C-219/15) at [51] – [53].

<sup>24</sup> *Schmitt* (C-219/15) at [55].

<sup>25</sup> *Peter Paul and others v Bundesrepublik Deutschland* (C-222/02) ECLI:EU:C:2004:606.

<sup>26</sup> *Schmitt* (C-219/15) at [56] – [57].

Directive – are governed by national law, subject to the principles of equivalence and effectiveness.<sup>27</sup>

### **No EU law-based liability of notified bodies**

It follows from the judgment in *Schmitt* that the CJEU does not consider the Medical Devices Directive to provide a right to end users to hold notified bodies liable. However, its reliance on its previous judgment in *Paul* to support this is not uncontroversial. In *Paul*, the CJEU held that the fact that public supervisory agencies in financial markets acted in the interests of depositors did not mean that depositors also had a right to hold the supervisory agencies liable. Its reasoning was twofold: first, the relevant directive did not expressly grant such a right;<sup>28</sup> second, the coordination of national rules on the liability of public agencies was not necessary to ensure the *effet utile* of the relevant EU legislation.<sup>29</sup> In *Schmitt*, the CJEU only focussed on the wording of the Medical Devices Directive. As such, the way in which *Paul* was applied was minimalistic. The CJEU did not place the Medical Devices Directive in the broader context of the regulatory approach of which it formed part. The question whether the liability of notified bodies was necessary to guarantee the effective functioning of the Medical Devices Directive in the context of the New Approach was not analysed. Similarly, the CJEU did not analyse whether the limited scope of the Product Liability Directive, which only provides for strict liability of manufacturers and parties who may be considered as such, requires that EU law should create an additional type of liability to guarantee that end users are adequately protected and are able to obtain damages if they suffer personal injury or property damage as a result of defective medical devices.

Norbert Reich has argued very strongly that the reasoning in *Paul* should not be applied to the liability of notified bodies.<sup>30</sup> He relied on the preambles of the Medical Devices Directive, which

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<sup>27</sup> *Schmitt* (C-219/15) at [58] – [59].

<sup>28</sup> *Paul* (C-222/02) at [41].

<sup>29</sup> *Paul* (C-222/02) at [42] – [44].

<sup>30</sup> Reich, “Product Liability and Beyond: An Exercise in ‘Gap-Filling’” (2016) 24 European Review of Private Law 619, 638.

stated that “medical devices should provide patients, users and third parties with a high level of protection”.<sup>31</sup> The difference between *Paul* and *Schmitt* was that, in *Paul*, holding public supervisory agencies liable would go against the very aim of the applicable EU legislation, which was to create a single licence system for credit institutions. The Medical Devices Directive, on the contrary, explicitly identified the protection of end users as one of its objectives. Moreover, according to Reich, *Paul* was too specifically focussed on banking supervision for the judgment to be applied to *Schmitt*.<sup>32</sup> This was also the conclusion of Advocate General Sharpston, who had rejected the arguments of the German State to apply the judgment by analogy.<sup>33</sup>

Nevertheless, the CJEU has now applied *Paul* in the context of medical devices. The question remains whether it has only focussed on the provisions of the Medical Devices Directive – which could be seen as the first step of the CJEU’s approach in *Paul* –, or whether it has also implicitly rejected the more fundamental argument that liability of notified bodies is required to protect the *effet utile* of the Medical Devices Directive – the second step in *Paul*. The CJEU recognised that the protection of end users is one of its aims. Nevertheless, this objective does not provide end users with a right of compensation vis-à-vis notified bodies. As such, a somewhat artificial distinction is made between the obligation of notified bodies to protect end users and the right of those end users to hold notified bodies liable if they breach that obligation. In free movement law, the CJEU has held that a directly effective obligation on the part of a Member State or individual has as its corollary a right of the beneficiary of that obligation and, under certain circumstances, even an effective remedy.<sup>34</sup> It may be that the CJEU did not find it necessary to go deeper into this question, because it knew that its conclusion that notified bodies perform the

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<sup>31</sup> Preambles of the Medical Devices Directive.

<sup>32</sup> Reich, “Product Liability and Beyond: An Exercise in ‘Gap-Filling’” (2016) 24 European Review of Private Law 619, 635.

<sup>33</sup> Opinion of Advocate General Sharpston in *Schmitt* (C-219/15) ECLI:EU:C:2016:694, at fn 27.

<sup>34</sup> In the famous *Joined Cases of Brasserie du Pêcheur and Factortame III* the CJEU held that: ‘in the event of infringement of a right directly conferred by a Community provision upon which individuals are entitled to rely before the national courts (...) the right to reparation is the necessary corollary of the direct effect of the Community provision whose breach caused the damage sustained’: *Brasserie du Pêcheur SA v Bundesrepublik Deutschland* (C-46/93) and *The Queen v Secretary of State for Transport, ex parte: Factortame Ltd and others* (C-48/93), ECLI:EU:C:1996:79, at [22].

conformity assessment procedure with the aim to protect end users would be sufficient for the Bundesgerichtshof to tackle the question under German tort law as regards the protective scope of the statutory rules at play (*Schutzgesetz*). However, this does not provide a strong justification to refuse to engage with the more fundamental question.

The CJEU's reasoning in *Schmitt* demonstrates that the main objective of the New Approach, as shown by the legal basis of the Medical Devices Directive,<sup>35</sup> is to improve free movement of goods in the EU, and not the safety of products.<sup>36</sup> While the protection of end users is one of its aims, this aim is secondary to the primary aim of improving the internal market for goods.<sup>37</sup> The *effet utile* of the New Approach does not require that the potential liability of notified bodies to end users is regulated by EU law itself – the protection of this aim can be left to national law.

Finally, the CJEU concludes that the conditions governing the liability of notified bodies under national private law are subject to the principles of equivalence and effectiveness.<sup>38</sup> Here, the Court's artificial distinction between rights and obligations comes back to bite. According to the Court, we are in the realm of procedural autonomy. However, one wonders why the principles of equivalence and effectiveness are applicable if the Court held that there is no EU-law right for end users to claim compensation from notified bodies. The principles of equivalence and effectiveness limit the procedural autonomy of Member State in ensuring that a subjective right granted by EU law can be effectively relied upon before national courts or other state-based enforcement mechanisms. In *Schmitt*, the CJEU squarely rejected the existence of such a right. The only way to explain the CJEU's reference to the principles of equivalence and effectiveness would be to say that the Medical Devices Directive provides an "abstract" right of protection to

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<sup>35</sup> Article 100a EEC (now Article 114 TFEU).

<sup>36</sup> A. McGee and S. Weatherill, "The Evolution of the Single Market – Harmonisation or Liberalisation?" (1990) 53 *Modern Law Review* 578, 586-587. See for an early analysis of the relationship between free movement of goods and product safety in the New Approach J. Pelkmans, "The New Approach to Technical Harmonization and Standardization" (1987) 25 *Journal of Common Market Studies* 249.

<sup>37</sup> Van Leeuwen, "PIP Breast Implants, the EU's New Approach for Goods and Market Surveillance by Notified Bodies" (2014) 5 *European Journal of Risk Regulation* 338, 349. See also C. Joerges, J. Falke and H. Micklitz, *Die Sicherheit von Konsumgütern und die Entwicklung der Europäischen Gemeinschaft* (Baden-Baden: Nomos, 1988) and N. Reich, "AGM-COS.MET or: who is protected by EC safety regulation?" (2008) 33 *European Law Review* 85.

<sup>38</sup> *Schmitt* (C-219/15) at [59].

end users, which brings the case within the scope of procedural autonomy.<sup>39</sup> By way of speculation, it might be said that Article 19(1) TEU and Article 47 of the Charter of Fundamental Rights have played an important role in increasing the scope of application of the principles of procedural autonomy. After all, Article 19(1) provides that “Member States shall provide remedies sufficient to ensure legal protection in the fields covered by Union law”. This obligation is reinforced by the right to an effective remedy in Article 47 of the Charter. The precise relationship between these rights and the principles of equivalence and effectiveness remains uncertain.<sup>40</sup> Nevertheless, bringing the case within the scope of procedural autonomy does not seem consistent with the main reasoning of the CJEU. It merely looks like an attempt to keep some level of EU control in a field where EU law has just withdrawn from.

### **The impact of *Schmitt* on national damage actions**

According to the CJEU, the liability of TÜV vis-à-vis women who received PIP breast implants is governed by national private law. What implications does the judgment have in that national context? Does it improve the chances of the women to obtain compensation for the harm they suffered based on national law? Will it result in consistent outcomes across different Member States? These questions gain practical importance, since damage actions against TÜV have also been brought in France. More than 20 000 women around the world have opted in to join the latest French collective action.

#### *German*

<sup>39</sup> S. Weatherill, “Compulsory Notification of Draft Technical Regulations: the Contribution of Directive 83/189 to the Management of the Internal Market” (1996) 16 Yearbook of European Law 129, 198-202. See in general W. van Gerven, “Of Rights, Remedies and Procedures” (2000) 37 Common Market Law Review 501 and H. Schebesta, “Procedural Theory in EU Law” in K. Purnhagen and P. Rott, *Varieties of Economic Law and Regulation* (Heidelberg: Springer, 2014), 851-862, 856.

<sup>40</sup> See *Rosalba Alassini v Telecom Italia SpA* (C-318/08), ECLI:EU:C:2010:146 and *Unibet (London) Ltd and Unibet (International) Ltd v Justitiekanslern* (C-432/05), ECLI:EU:C:2007:163. See for more extensive analysis e.g. M. Safjan and D. Düsterhaus, “A Union of Effective Judicial Protection: Addressing a Multi-level Challenge through the Lens of Article 47 CFREU” (2014) 33 Yearbook of European Law 3, A. Arnall, “The Principle of Effective Judicial Protection in EU law: An Unruly Horse?” (2011) 36 European Law Review 51 and S. Prechal and R. Widdershoven, “Redefining the Relationship between ‘Rewe-effectiveness’ and effective judicial protection” (2011) 4 Review of European Administrative Law 31. J. Krommendijk “Is there light on the horizon? The distinction between ‘Rewe-effectiveness’ and the principle of effective judicial protection in Article 47 of the Charter after Orizzonte” (2016) 53 Common Market Law Review 1395.



One ground for Ms. Schmitt to establish the liability of TÜV for the damage she suffered is to show that TÜV violated its statutory rules under the Medical Devices Directive as transposed in national law (*Medizinproduktegesetz*). To be successful in that claim, German tort law, under the concept of *Schutzgesetz* of § 823 II BGB, requires as a matter of principle that, the statutory rules allegedly violated by TÜV protect the interests of Ms Schmitt.<sup>41</sup> The CJEU's judgment makes it clear that Ms Schmitt and women like her – as end users of PIP breast implants – are within the protective scope of the Medical Devices Directive and, by extension, the *Medizinproduktegesetz*.

~~One ground for Ms. Schmitt to establish the liability of TÜV for the damage they suffered is to show that TÜV violated its statutory obligations under the Medical Devices Directive as transposed in national law. As noted, here German tort law requires that the violated statutory rule protects the interests of Ms Schmitt (*Schutzgesetz*).<sup>42</sup> The CJEU's judgment makes it clear that women like Ms Schmitt – as end users of PIP breast implants – are within that protective scope.~~

As a result, TÜV was under an obligation to take into account the legitimate interests of potential users of the implants when it performed conformity assessment procedures at PIP ~~under the Medical Devices Directive~~.<sup>43</sup> Before, the German Court of Appeal had concluded that Ms Schmitt was not within the protective scope of the statutory rules and had dismissed her action for this reason.<sup>44</sup>

While the CJEU's judgment removes one important obstacle for victims to hold TÜV liable based on German private law, this does not necessarily mean that their damage actions will be successful. To obtain damages, they still have to prove that TÜV breached its duty of care and that this breach was attributable to it. In the case of Ms Schmitt, the Court of Appeal previously

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<sup>41</sup> § 823 II *Bürgerliches Gesetzbuch*. See also at n 15 *supra*.

<sup>42</sup> See at n 15 *supra*.

<sup>43</sup> *Schmitt* (C-219/15) at [50] – [53]. See also P. Rott, “Pflichten und Haftung der “benannten Stelle” bei Hochrisiko-Medizinprodukten (2017) *Neue Juristische Wochenschrift* 1146, 1147.

<sup>44</sup> Judgment of the Oberlandesgericht Zweibrücken of 30 January 2014 – 4 U 66/13, para II.2 b) bb) and para II.3 d). Rott and Glinski already suggested this interpretation of the court of appeal was false. See Rott and Glinski, “Die Haftung der Zertifizierungsstelle im Produktsicherheitsrecht” (2015) *Zeitschrift für Europäisches Privatrecht* 192, 204.

held that that was no breach of the obligations TÜV owed under the national legislation which had implemented the Medical Devices Directive. Even if there had been a breach, the condition of culpability could not be established given the cunning nature of PIP's fraud and given the fact that PIP had even been successful in hiding the fraud from the French public authorities.<sup>45</sup>

The Bundesgerichtshof followed the Court of Appeal in this regard when it delivered its final judgment on 22 June 2017. It considered that no statutory duties had been violated.<sup>46</sup> Based on the submissions of Ms Schmitt as allowed under German civil procedural law, it could not be held that TÜV knew or should have known about PIP's non-compliance prior to the moment she received PIP breast implants.<sup>47</sup> Since the [Bundesgerichtshof](#) ~~BGH~~ concluded that no statutory duties had been violated and that TÜV is thus not liable to Ms Schmitt, the question of whether liability could be based either on German contract law or tort law [for breach of statutory rules](#) did not require discussion.<sup>48</sup>

### *France*

The CJEU's judgment in *Schmitt* is also of importance to the damage actions brought against TÜV in France.<sup>49</sup> In 2013, the District Court of Toulon held in a collective action brought by 1 599 victims from Brazil, France and the UK, as well as six distributors of PIP breast implants,

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<sup>45</sup> Judgment of the Oberlandesgericht Zweibrücken of 30 January 2014 – 4 U 66/13, para. II.3 d) en e). The district court considered that Ms Schmitt would face difficulties in meeting the standard of proof for causation: Judgment of the Landgericht Frankenthal (Pfalz) of 14 March 2013 – 6 O 304/12, 138.

<sup>46</sup> Judgment of the Bundesgerichtshof of 22 June 2017 – VII ZR 36/14, at [26] – [29].

<sup>47</sup> Judgment of the Bundesgerichtshof of 22 June 2017 – VII ZR 36/14, at [30] – [33]. It is unclear what evidence could possibly establish such non-compliance. The CJEU nor the Medical Devices Directive provide any guidance to the national court. This is a salient issue. Given that the CJEU has held that there is no obligation on the part of TÜV to perform unannounced inspections, the question arises how TÜV could have known about the fraud other than from public sources of information. It is very unlikely that a certification body like TÜV will discover non-compliance like PIP's fraud only through announced inspections. The purpose of certification under the New Approach (and in general) is not to detect fraud. Its success largely depends on the willingness of regulated firms to play by the rules. See G. Jahn, M. Schramm and A. Spiller, "The Reliability of Certification: Quality Labels as a Consumer Policy Tool" (2005) 28 *Journal of Consumer Policy* 53, 55-56.

<sup>48</sup> Judgment of the Bundesgerichtshof of 22 June 2017 – VII ZR 36/14, at [36].

<sup>49</sup> See, for a more detailed analysis, Van Leeuwen, "PIP Breast Implants, the EU's New Approach for Goods and Market Surveillance by Notified Bodies" (2014) 5 *European Journal of Risk Regulation* 339, 345-346, and De Bruyne and Vanleenhove, "Liability in the Medical Sector: The 'Breast-Taking' Consequences of the Poly Implant Prothèse Case" (2016) 24 *European Review of Private Law* 823, 839-840.

that TÜV had breached its statutory duty “de contrôle, de surveillance et de vigilance”.<sup>50</sup> Since French private law does not know a concept like *Schutzgesetz*, the district court was not troubled with the question of the protective scope of the national laws implementing the Medical Devices Directive.<sup>51</sup> It held that TÜV should have used its powers under these national laws more effectively. If it had done so, the fraud would have been discovered. The district court also considered that TÜV had been required to take action after the finding of the US *Food and Drug Administration* in 2000 that PIP was using industrial silicone gel to manufacture breast implants. After this discovery, PIP breast implants were banned in the United States. The Toulon court finally awarded interim damages of about EUR 3 000 to each claimant.

The Court of Appeal in Aix-en-Provence reversed the Toulon judgment. It held that the Medical Devices Directive did not create any obligation for TÜV to physically inspect implants and that the information provided by PIP did not provide any reason to conduct additional tests or unannounced inspections. As a result, TÜV had complied with its obligations under the Directive and had not acted wrongfully vis-à-vis the plaintiffs.<sup>52</sup> Like the German Court of Appeal, the Aix-en-Provence Court held that the cunning nature of PIP’s fraud meant that it could not have been expected that TÜV would have discovered the fraud.<sup>53</sup> The findings of the US authorities in 2000 were considered irrelevant.<sup>54</sup>

In January 2017, the District Court of Toulon delivered its judgment in another collective action, now brought by over 20,000 victims from 14 countries, 8 distributors of PIP breast implants and 25 medical facilities that had provided PIP implants to women.<sup>55</sup> Again, the Toulon Court held TÜV liable and awarded interim damages to the claimants. In doing so, it followed the same

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<sup>50</sup> Judgment of the Tribunal de Commerce de Toulon of 14 November 2013, 2011F00517, p. 142.

<sup>51</sup> See also Rott and Glinski, “Die Haftung der Zertifizierungsstelle im Produktsicherheitsrecht” (2015) *Zeitschrift für Europäisches Privatrecht* 192, 203-204.

<sup>52</sup> Judgment of the Court of Appeal of Aix-en-Provence of 2 July 2015, 13/22482, p. 109, 113 and 119.

<sup>53</sup> Judgment of the Court of Appeal of Aix-en-Provence of 2 July 2015, 13/22482, p. 121-125.

<sup>54</sup> Judgment of the Court of Appeal of Aix-en-Provence of 2 July 2015, 13/22482, p. 121-122.

<sup>55</sup> Judgment of the Tribunal de Commerce de Toulon of 20 January 2017, 2014F00306, p. 307, 358, 367 and 396. See <http://fr.reuters.com/article/frEuroRpt/idFRL5N1FA3TY?pageNumber=1&virtualBrandChannel=0>.

reasoning as it had done in the collective action in 2013. It did not refer in any way to the judgment of the Aix-en-Provence Court of Appeal.<sup>56</sup> TÜV has appealed this judgment.

*Schmitt* is also important to the French litigation since the CJEU, unlike the Court of Appeal in Aix-en-Provence, laid down a general obligation to act with all due diligence in performing conformity assessment procedures. The French courts will now have to assess – similarly to what the Bundesgerichtshof did in its final judgment – whether TÜV complied with that obligation in the circumstances of the case. Again, the key question is whether and when TÜV could be considered to have known about PIP’s non-compliance and what measures it took in response. Given that this question is of a highly factual nature, it might be that, due to the different facts in the damage actions and differences in the applicable conditions for liability and standards of proof under French civil (procedural) law, a French court will reach a different conclusion on this issue from the Bundesgerichtshof. As such, uniformity as regards the liability of TÜV in Europe is anything but guaranteed.

### **The regulation of medical devices in the EU after *Schmitt***

In 2012, after the PIP scandal, the European Commission published a proposal for a new Regulation on medical devices, which would replace the Medical Devices Directive.<sup>57</sup> In April 2017, the final version of the Regulation was approved by the European Parliament.<sup>58</sup> The Regulation will come into force in May 2020 and includes a number of important changes with regard to the obligations of notified bodies. Interestingly, all obligations which Ms Schmitt claimed notified bodies had under the Medical Devices Directive, have now been expressly incorporated in the Regulation.<sup>59</sup> Notified bodies will have to carry out unannounced inspections

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<sup>56</sup> Judgment of the Tribunal de Commerce de Toulon of 20 January 2017, 2014F00306, p. 39-41.

<sup>57</sup> European Commission, “Proposal for a Regulation on medical devices” COM(2012) 542 final.

<sup>58</sup> Regulation 2017/745 of the European Parliament and the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.

<sup>59</sup> One could say that this implicitly confirms that as a notified body TÜV was not obliged to carry out unannounced inspections at PIP and to physically inspect the PIP breast implants under the conformity assessment regime of the Medical Devices Directive.

at least once in every five year.<sup>60</sup> During these inspections, they are obliged to take samples of the certified products to assess whether they comply with the design dossier.<sup>61</sup> Moreover, notified bodies have to verify that the amount of raw materials used by the manufacturer is consistent with the number of products which have been manufactured.<sup>62</sup> Beyond the conformity assessment procedure, notified bodies will have to satisfy new requirements as regards *inter alia* their organisational structure, independence and impartiality, qualifications of personnel and contracted experts.<sup>63</sup> Furthermore, the supervision of notified bodies by Member States is intensified.<sup>64</sup> The Regulation also provides that a European database for medical devices should be created, so that medical devices can be traced from the moment of production until the end user.<sup>65</sup> Again, the new Regulation does not provide for rules on the private law liability of notified bodies.

*Schmitt* could be seen as an attempt to streamline the transition process from the Medical Devices Directive to the new Regulation. The judgment defines the obligations of notified bodies until the coming into force of the Regulation in 2020. *Schmitt* makes it clear that, until that time, notified bodies have to take action if they receive information which suggests that medical devices may no longer comply with the relevant European legislation.<sup>66</sup> In such cases, they have to make full use of the powers given to them under the Directive, such as carry out unannounced on-site inspections or conduct physical tests on devices. No general obligation exists to organise such inspections or tests until the new Regulation comes into force.<sup>67</sup> However, the general obligation imposed on notified bodies in *Schmitt* on the basis of the Medical Devices Directive to do all they reasonably can to ensure that the declaration of conformity is valid will most likely

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<sup>60</sup> Article 3.4 of Annex IX of Regulation 2017/745 .

<sup>61</sup> Article 3.4 of Annex IX of Regulation 2017/745

<sup>62</sup> Article 3.5 of Annex IX of Regulation 2017/745.

<sup>63</sup> Articles 1.1, 1.2, 3.2 and 3.4 of Annex VII of Regulation 2017/745.

<sup>64</sup> Articles 44 and 45 of Regulation 2017/745.

<sup>65</sup> Articles 27 – 29 of Regulation 2017/745.

<sup>66</sup> *Schmitt* (C-219/15) at [47] – [48]. These obligations follow from Article 16(6) of the Medical Devices Directive and are focussed on the question of whether the medical devices should still be allowed to be placed on the EU market (market access).

<sup>67</sup> *Schmitt* (C-219/15) at [40].

continue to apply under the new Regulation. Like the Directive, the Regulation provides that the assessment activities of notified bodies are aimed at ensuring that the manufacturer meets – and continues to meet – the requirements as set out in the Regulation and that these bodies must suspend or withdraw the certificate, or impose any other appropriate restrictions on it, if the manufacturer no longer meets those requirements.<sup>68</sup>

### **Constitutionalisation of private regulation**

As a final consideration of the implications of *Schmitt*, we argue that this judgment is to be understood as being part of a broader trend in the case law of the CJEU, in which it has gradually submitted private standardisation and certification activities to fundamental principles of EU law. This “constitutionalisation” of private regulation clearly emerged in *Fra.bo* and, more recently, in *James Elliott*. In *Schmitt*, the CJEU continues along this path and adds that notified bodies acting under the New Approach owe a duty of care to end users of products.<sup>69</sup>

#### *James Elliott*

In November 2016, the CJEU delivered its judgment in *James Elliott*.<sup>70</sup> This case concerned a private law dispute about the interpretation of a European harmonised standard for construction materials. This standard had been developed under the New Approach. The national version of the standard was incorporated in a sales contract between a construction company, James Elliott, and a supplier of concrete to be used in the Irish construction sector, Irish Asphalt. James Elliott had used concrete supplied by Irish Asphalt in the construction of a youth facility. After a certain

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<sup>68</sup> See Article 56(4) of Regulation 2017/745 and Articles 2.3, 3.1 and 3.7 of Annex IX of Regulation 2017/745.

<sup>69</sup> Arguably, *A.G.M.-COS.MET*, which concerned the liability of the Finnish State for unauthorized safety warnings by one of its public officials concerning an Italian product bearing the CE marking, could also be considered part of this line of case law. However, in this case, the CJEU did not explicitly assess the standardisation and certification activities involved in the light of EU law. Instead, it chose to focus entirely on the matter of State liability for breach of EU law. *A.G.M.-COS.MET Srl v Suomen valtio and Tarmo Lehtinen* (C-470/03) ECLI:EU:C:2007:213 at [74] as discussed by N. Reich, “AGM-COS.MET or: who is protected by EC safety regulation?” (2008) 33 *European Law Review* 85, 89.

<sup>70</sup> *James Elliott Construction Ltd v Irish Asphalt Ltd* (C-613/14) ECLI:EU:C:2016:821. See, for more detailed analysis, A. Volpato, “Harmonised standards before the ECJ: James Elliott Construction” (2017) 54 *Common Market Law Review* 591 and K. Purnhagen, “Voluntary “New Approach” Technical Standards are Subject to Judicial Scrutiny by the CJEU! – The Remarkable CJEU judgment “Elliott” on Private Standards” 2017/05 *Wageningen Working Papers in Law and Governance*, available at: <https://ssrn.com/abstract=2988895>.

period of time, the concrete floors and ceilings of the facility started to show cracks. This was caused by the chemical composition of the supplied concrete. James Elliott argued that Irish Asphalt had breached its obligations under national sales law to supply construction materials of “merchantable quality” which were “fit for purpose”.

The defence of Irish Asphalt turned this very national sales law dispute into a major case for EU constitutional law. Irish Asphalt argued that the European standard incorporated in the sales contract laid down methods to establish how and when a product complied with the technical specifications in the standard. Therefore, the question arose which rules – either national sales law or the European standard – determined the conformity of the products supplied. Irish Asphalt argued that the relevant harmonised standard should be considered as EU law. As a result, it should have primacy over national sales law and preclude national sales law from imposing additional conditions such as “merchantable quality” and “fit for purpose” on suppliers to determine the conformity of the supplied construction materials. The first question for the CJEU was therefore whether harmonised standards adopted under the New Approach were part of EU law, and as such, whether it had jurisdiction to give a preliminary ruling on the interpretation of these standards.

The CJEU answered this first question in the positive. This was despite the fact that harmonised standards are developed by organisations which are governed by private law and are not institutions, bodies, offices or agencies of the Union. Similarly, it did not matter that these standards have no binding legal status. The CJEU held that these standards are part of EU law because they are measures implementing or applying an act of EU law. After all, the Commission publishes their references in the OJEU and they have a legal effect under the New Approach.<sup>71</sup>

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<sup>71</sup> *Elliott* (C-613/14) at [34], [37] and [42].

For this reason, *James Elliott* has an important constitutional dimension: harmonised standards are part of EU law and the CJEU has the ultimate authority over their interpretation.<sup>72</sup>

A key consequence of *James Elliott* is that individual contracting parties, within the context of a preliminary reference procedure, can now ask the CJEU about the validity and interpretation of European harmonised standards in disputes over the performance of a contract.<sup>73</sup> While the CJEU did not review the substance of the harmonised standard at issue in this case,<sup>74</sup> it provided an interpretation of the private standard which was required for the outcome of the underlying contractual dispute.<sup>75</sup> Despite the fact that the disputing parties may not have been involved in the adoption of the European standard, they can now challenge the validity and interpretation of such a standard through the preliminary reference procedure. Seen in this way, *James Elliott* enables third parties to obtain effective judicial protection against the influence private standards have on their legal position in private law disputes. It thus constitutionalises private standardisation within the New Approach.

This process of constitutionalisation raises various institutional issues. First of all, one can wonder how the CJEU should go about interpreting harmonised standards. Inevitably, questions will come up that go to the very substance of the standards. Do its judges possess the necessary skills to review this substance? What standard of review applies?<sup>76</sup> The Court will need to sort out how it will organise its review. In *James Elliott* it remains unclear how it will do so. Second, the question arises of whether the preliminary reference procedure is the right forum to provide effective judicial protection to private parties against private standardisation. Would this not change the character of the preliminary reference procedure from a procedure about the validity

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<sup>72</sup> *Elliott* (C-613/14) at [40].

<sup>73</sup> *Elliott* (C-613/14) at [48] – [53].

<sup>74</sup> *Elliott* (C-613/14) at [51].

<sup>75</sup> Where in *James Elliott* the dispute was about the performance of a contract, compliance with a harmonized standard may also be of relevance in tort law actions. See, in detail, Schepel, *The Constitution of Private Governance* (Oxford: Hart Publishing, 2005), pp. 339ff.

<sup>76</sup> See, in the same vein, Schepel, “The new approach to the New Approach: the juridification of harmonised standards in EU law” (2013) 20 Maastricht Journal of European and Comparative Law 521, 532-533.



and correct interpretation of EU law into a so-called “*citizens’ infringement procedure*”?<sup>77</sup> Third, Van Gestel and Micklitz have argued that by providing effective judicial protection against private standardisation bodies, the walls of these bodies’ “club houses” will break down. In their argument, an increased influence of public law – whether national constitutional law or EU law – on private standardisation requires a rethinking of the organisation of this form of private regulation.<sup>78</sup> In *James Elliott*, the CJEU did not address this issue of the governance of private standardisation. How will the judgment affect the internal procedures and business models of private standardisation bodies?<sup>79</sup>

One particularly important issue on this last point is that private standardisation bodies own the copyright in their standards. They argue that their business models are to a significant extent based on the revenues they earn from selling their standards – which are copyright-protected – to end users.<sup>80</sup> Since it is not normally possible to protect legislation by copyright and harmonised standards are now considered part of EU law, the question of whether these bodies can continue to apply the same business model is evident.<sup>81</sup> However, the judgment in *Elliott* is of no help in answering this question.<sup>82</sup> As a result, we will have to wait for a new case for the CJEU to have an opportunity to address this issue.

*Fra.bo*

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<sup>77</sup> See, in general, B. de Witte, “The preliminary ruling dialogue: the types of questions posed by national courts”, in B. de Witte et al. (eds.), *National Courts and EU Law: New Issues, Theories and Methods* (Cheltenham: Edward Elgar, 2016) pp. 15-25.

<sup>78</sup> R. van Gestel and H.-W. Micklitz, “European integration through standardization: How judicial review is breaking down the club house of private standardization bodies” (2013) 50 *Common Market Law Review* 145.

<sup>79</sup> See also Volpato, “Harmonised standards before the ECJ: James Elliott Construction” (2017) 54 *Common Market Law Review* 591, 601-602 and Purnhagen, “Voluntary “New Approach” Technical Standards are Subject to Judicial Scrutiny by the CJEU! – The Remarkable CJEU judgment “Elliott” on Private Standards” 2017/05 Wageningen Working Papers in Law and Governance, available at: <https://ssrn.com/abstract=2988895>.

<sup>80</sup> See Van Gestel and Micklitz, “European integration through standardization: How judicial review is breaking down the club house of private standardization bodies” (2013) 50 *Common Market Law Review* 145, 160ff.

<sup>81</sup> See Volpato, “Harmonised standards before the ECJ: James Elliott Construction” (2017) 54 *Common Market Law Review* 591, 598-599.

<sup>82</sup> Advocate-General Campos Sanchez-Bordona did consider the matter in his Opinion in *James Elliot* (at [51]). He noted briefly that the inclusion of harmonised standards within the scope of EU would have “a very significant impact on the European standardisation system”. However, he did not find it necessary to consider this question in detail.

The CJEU has also applied EU law to private standardisation and certification activities in a different context. This happened in *Fra.bo*,<sup>83</sup> which was about a contractual dispute between Fra.bo, an Italian manufacturer of copper fittings, and the Vereinigung des Gas- und Wasserfaches (DVGW), a German not-for-profit association which developed technical standards for the national gas and water sector. Fra.bo sought to place its copper fittings for the gas and water sector on the German market, but under German law it first had to obtain a safety certificate. In practice, for Fra.bo, certification by DVGW was the only way to obtain this certificate. Therefore, the Italian firm concluded a contract with DVGW to have its fittings certified. However, in the performance of the contract, DVGW refused to recognise the positive test results on the basis of which Fra.bo's fittings were lawfully traded in Italy. As a result, Fra.bo was denied access to the German market.

Fra.bo then sued DVGW for a breach of contract. In this context, it argued that DVGW had breached Article 34 TFEU, which prohibits quantitative restrictions on import and all measures having equivalent effect. While the CJEU had previously held that Article 34 TFEU did not have horizontal direct effect and could therefore not apply to contractual arrangements,<sup>84</sup> in *Fra.bo* it opened the door for Article 34 TFEU to have horizontal direct effect. Despite the fact that DVGW was a body governed by private law, the CJEU held that, given its authority to certify products, it *de facto* had the power to regulate access to the German market.<sup>85</sup> Consequently, DVGW's standardisation and certification activities – exercised through the contract concluded with Fra.bo – were held to be subject to the prohibition laid down in Article 34 TFEU.<sup>86</sup>

*Fra.bo* makes it clear that even private standardisation and certification activities which take place outside the scope of the New Approach cannot escape review under Article 34 TFEU provided

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<sup>83</sup> *Fra.bo SpA v DVGW eV* (C-171/11), ECLI:EU:C:2012:453.

<sup>84</sup> See extensively C. Krenn, "A Missing Piece in the Horizontal Effect 'Jigsaw': Horizontal Direct Effect and the Free Movement of Goods" (2012) 49 Common Market Law Review 177.

<sup>85</sup> *Fra.bo* (C-171/11) at [27] – [31].

<sup>86</sup> See L. Gormley, "Private Parties and the Free Movement of Goods: Responsible, Irresponsible, or a Lack of Principles" (2015) 38 Fordham International Law Journal 993, 1001-1003. See also B. van Leeuwen, "Private Regulation and Public Responsibility in the Internal Market" (2014) 33 Yearbook of European Law 277.

that national law attributes an important role to the certification in obtaining access to the market.<sup>87</sup> For the contractual dispute between Fra.bo and DVGW, the CJEU's judgment implied that the certification body could not impose additional discriminatory conditions on Fra.bo that would impede access to the German market. More specifically, DVGW had to recognize the positive test results provided by Fra.bo on the basis of which its products were legally traded in Italy, and as such, had to award the required certificate. By refusing to do so, it breached its contractual obligations vis-à-vis Fra.bo.<sup>88</sup>

### *Back to Schmitt*

*Schmitt* adds to *Fra.bo* and *James Elliot* that notified bodies acting under the New Approach are required to act with all due diligence in conducting conformity assessment procedures.<sup>89</sup> This duty fundamentally limits the margin of discretion notified bodies possess based on their expertise and professionalism in verifying and keeping under surveillance products and manufacturers. Notified bodies must now take all necessary steps to ensure the correctness of the declaration of conformity. As such, the CJEU has introduced a new duty of care owed to end users of products for notified bodies within the New Approach. A breach of this duty may give rise to civil liability under national law, which is required to provide effective remedies against the breach of their duty of care. Accordingly, the CJEU has imposed another control mechanism on private regulatory activities that fall within the scope of EU law.

In conclusion, it follows from the trilogy of *Fra.bo*, *James Elliot* and *Schmitt* that the CJEU submits forms of private regulation to fundamental principles of EU law (effective judicial protection,

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<sup>87</sup> *Fra.bo* has triggered discussions around the question of whether and to what extent the CJEU has now brought the free movement of goods in line with the free movement of persons and services, for which the Court has long accepted that these freedoms have horizontal direct effect. See for elaborate discussions on this question H. van Harten and T. Nauta, "Towards horizontal direct effect for the free movement of goods? Comment on *Fra.bo*" (2013) 38 *European Law Review* 677, 686-689, B. van Leeuwen, "From Status to Impact, and the Role of National Legislation: The Application of Article 34 TFEU to a Private Certification Organisation in *Fra.bo*" (2013) 4 *European Journal of Risk Regulation* 405 and P. Verbruggen, 'The Impact of Free Movement of Goods and Services on Private Law Rights and Remedies' in H-W. Micklitz and C. Sieburgh (eds.), *Primary EU Law and Private Law Concepts* (Cambridge: Intersentia, 2017), pp. 47-91.

<sup>88</sup> Judgment of the Oberlandesgericht Düsseldorf of 14 August 2013, VI-2 U (Kart), [48] – [54].

<sup>89</sup> *Schmitt* (C-219/15) at [46].

free movement law) whenever private regulation affects the legal position of individuals who seek to gain access to the European market or who fall victim to regulatory activities on that market which are exercised by private parties. This constitutionalisation of private regulation is unavoidable. A growing influence of private standardisation and certification in public life calls for a stronger degree of public accountability.<sup>90</sup> Some have doubted whether this development is a positive one. Schepel, for example, argued after *Fra.bo* that this judgment would sooner “paralyse” European standardisation than that it would strengthen its integrity.<sup>91</sup> Constitutionalisation indeed carries with it the risk that private standardisation and certification, which were introduced as alternatives to public regulation, eventually assume the same characteristics of precisely that type of regulation. As a result, they may lose their appeal – both for the industry and for the legislature.<sup>92</sup> However, from the perspective of judicial protection, the judgments in *Schmitt*, *James Elliot* and *Fra.bo* should be welcomed. The CJEU more and more enables individuals who are subject to the influence of private standardisation and certification bodies to enforce their legitimate interests before national courts with the help of EU law.

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<sup>90</sup> Cf. J. Black, “Constitutionalising self-regulation” (1996) 1 *Modern Law Review* 24. See also Van Gestel and Micklitz, “European integration through standardization: how judicial review is breaking down the club house of private standardization bodies” (2013) 50 *Common Market Law Review* 145, 150.

<sup>91</sup> Schepel, “The new approach to the New Approach: the juridification of harmonised standards in EU law” (2013) 20 *Maastricht Journal of European and Comparative Law* 521, 533.

<sup>92</sup> See for an analysis of forms of private regulation encouraged under the EU Better Regulation programme: P. Verbruggen, “Private Regulation in EU Better Regulation: Past Performance and Future Promises” (2017) 19 *European Journal of Law Reform* 121.